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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,933	03/01/2001	Elisabeth Henriette Burger	702-002201	8311
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THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219				
			EXAMINER HEARD, THOMAS SWEENEY	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

09/720,933

Applicant(s)

BURGER ET AL.

Examiner

Thomas S. Heard

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/29/2006.
- 2a) ☒ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35 and 64-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35 and 64-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

The Applicants Amendments to the claims received on 9/29/2006 is acknowledged. The text of those sections of Title 35 U.S. Code not included in the action can be found in the prior office action. Rejections or objections not addressed in this office action with respect to the previous office action mailed 6/22/2006 are hereby withdrawn.

### ***Response to Arguments***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicant's arguments filed 9/29/2006 have been fully considered but they are not persuasive. Claims 35, 64-68 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S.

Patent No. 6,638,531 in view of Hamanishi et al, "A Self-Setting TTCP-DCPD Apatite Cement for Release of Vancomycin," Journal of Biomedical Research (applied Biomaterials), Vol. 33, 139-143 (1996), made of record in past Office Actions.

Applicants may overcome the Obviousness-Type Double Patenting by either canceling claims or filing a terminal disclaimer, see MPEP 804.02.

Applicants have argued that one of ordinary skill in the art would not have been motivated to combine the pharmaceutical composition of antimicrobial peptides disclosed in the '531 patent with the bone cement disclosed by Haminishi et al., because the pharmaceutical composition discussed therein solely is meant to administer antimicrobial peptides to a patient in need thereof to treat microbial infections rather than prevent or inhibit the bacterial infections. First, treating is inhibiting and preventing further growth and infection. Second, as stated in Hamanishi:

"Contamination of open wounds or postoperative deep infections following fracture repair, artificial joint replacement, or spinal instrumentation surgery caused by Methiciline-Cefem resistant Staphylococcus aureus (MSRA) has become a serious problem in orthopedic surgery," see first sentence of the article.

Therefore, individuals who are being operated on are simultaneously being infected and require antibiotic postoperative treatment. Additionally, other antibiotic drugs mixed with TTCP or bone material are also disclosed in Hamanishi in the discussion thereby making the invention of bone material combined with antibiotics known in the art and solving a serious problem.

Applicants argued that the bone material used by Hamanishi et al is not reabsorbable. On page 139, column 1 and line 18, TTCP-DCPD induces

Art Unit: 1654

osteoconduction and is also degraded and replaced by the host bone quickly.

Therefore, it is reabsorbable. Applicant's claims are drawn to a product and a method of making the product. All of the properties that are being argued by Applicant are inherent in the peptides, such as not leading to resistance. Further, Claim 1 and 8 of U.S. Patent No. 6,638,531 are drawn to the antimicrobial peptides instantly claimed in a pharmaceutically acceptable excipient, of which bone material is a pharmaceutically acceptable excipient. Finally, Applicants have stated they have an unexpected result, see page 5 and second paragraph. This argument is off point as the composition is already known so its unique properties of overcoming bacterial resistance is inherent to the peptide already patented, and not the bone material which is not an antibiotic.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 35 and 64-68 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Claims 35 and 64-68 stand rejected under 35 U.S.C. (g) based upon claims 1-3 of Patent No. 6,638,531.

Failure to present claims and/or take necessary steps for interference purposes after notification that interfering subject matter is claimed constitutes a disclaimer of the subject matter. This amounts to a concession that, as a matter of law, the patentee is the first inventor in this country. See *In re Oguie*, 517 F.2d 1382, 186 USPQ 227 (CCPA 1975).

Applicant's are on record in the remarks filed June 18, 2006, on page 2 and third paragraph as stating:

*In order to assert a double-patenting rejection, a patent or patent application and the application at issue must have common ownership. Applicants point out that the present invention and the '531 patent are not commonly owned, as they are assigned to different Assignees. Therefore, Applicants respectfully submit that an assertion of an obviousness-type double patenting rejection against this application in view of the '531 patent is not warranted and should be withdrawn (see page 2 of the response dated May 18, 2006).*

The MPEP states, the subject matter developed by another person and the claimed subject matter were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person or involved in a joint research agreement which meets the requirements of 35 U.S.C. 103(c)(2) and (c)(3). In this situation, a rejection under 35 U.S.C. 102(f) /103 or 102(g)/103, or 102(e) /103 for applications filed on or after November 29, 1999 >or pending on or after December 10, 2004<, is precluded (see MPEP 2137.01). Here, Applicants have admitted, on record, that the claimed invention in US 6,638,531 and the instant application did not have common ownership.

As a result, a question arises, under 102(f), as to the inventorship of the subject matter sought to be patented.

Evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to 35 U.S.C. 102 rejections and thus cannot

Art Unit: 1654

overcome a rejection so based. In re Wiggins, 488 F.2d 538, 543, 179 USPQ 421, 425 (CCPA 1973). The Applicants have not addressed the 35 USC § 102(f) or 102(g) rejection. Applicant's remarks regarding the 102(f) and 102(g) rejections have been solely directed to the Obviousness Type Double Patenting issue. Therefore, the rejections made of record in the previous office action mailed 6/22/2006 stand.

### **Conclusion**

No Claims Allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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